



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/548,408 | 07/27/2006 | Motohiro Takeda | 65,361-002 | 8009 |

27305 7590 03/25/2010
HOWARD & HOWARD ATTORNEYS PLLC
450 West Fourth Street
Royal Oak, MI 48067

| |
|----------|
| EXAMINER |
|----------|

CHENG, JACQUELINE

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3768

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

03/25/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/548,408 | Applicant(s) TAKEDA ET AL. | |
| | Examiner JACQUELINE CHENG | Art Unit 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/9/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 4, 2010 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's arguments that neither Klaveness (US 6,159,445) nor Snow (US 6,350,431) teaches the particles being capable of absorbing excitation light having a wavelength of less than 600 nm. The examiner believes that Klaveness teaches in col. 16 line 9-10 using fluorescent particles that have an emission maximum at a wavelength above 600 nm and in col. 16 line 32-34 the desirability of the particle to have an absorption maximum in the 400-1300 nm range for surface studies. Klaveness also discloses for detecting light such as transmitted light from an organ (col. 18 line 64-67) using excitation light of wavelengths from 100-1300 nm (col. 19 line 9-11). Furthermore Klaveness teaches using rhodamine as the fluorescent substance (col. 16 line 5), which is also disclosed as being used in the applicant's specification on page 10. Rhodamine also fulfills these limitations of capable of absorption of excitation light having a wavelength of less than 600 nm and fluorescing at a wavelength from 600-900 nm.

2. As to the applicant's arguments against Snow, the examiner respectfully disagrees with the applicant's arguments that the chromophores of Snow are disclosed as absorbing and emitting at the same wavelength. Snow states that the chromophores can have either an absorption or emission maximum in the wavelength range of 300-700 (col. 16 line 61-63). This does not state that they must absorb and emit at the same wavelength. This statement fulfills the claim language as it states that the chromophores of Snow are capable of absorbing excitation

Art Unit: 3768

light having a wavelength less than 600 (absorbing in the wavelength range of 300-700, i.e. 400 nm) and is capable of emitting fluorescence at a wavelength range from 600-900 nm (emitting in the wavelength range of 300-700, i.e. 600 nm). Furthermore Snow teaches using rhodamine as the chromophore (col. 16 line 32), which is also disclosed as being used in the applicant's specification on page 10. Rhodamine also fulfills these limitations of capable of absorption of excitation light having a wavelength of less than 600 nm and fluorescing at a wavelength from 600-900 nm.

3. It is for these reasons that it is believed that the previous rejection dated September 1, 2009 still stands and is repeated below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 2, 5, and 7** are rejected under 35 U.S.C. 102(b) as being anticipated by Klaveness (US 6,159,445). Klaveness discloses a method of generating an image of a human or of a small mammal other than a human being by administering a contrast agent to the body and create a light image of a region of interest (col. 8 line 3-10). The region of interest can be any part of the body such as for detection of a lymph node such as a sentinel lymph node (col. 10 line 37-40). The contrast agent can comprise a fluorophore which preferably has a characteristic emission in the 600-1300 nm range (col. 10 line 18-21), has a diameter of about 5 to 800 nm

Art Unit: 3768

(col. 17 line 6-11) and has an absorption maximum in the 400-1300 nm range (col. 16 line 32-34). In particular Klaveness discloses using a particle having a diameter of approximately 120 nm to image a rat (col. 28 line 22-30).

6. **Claims 1, 2, 5, and 7** are rejected under 35 U.S.C. 102(b) as being anticipated by Snow (US 6,350,431 B1). Snow discloses compounds that are useful as contrast agents in light imaging procedures, in particular compounds containing a plurality of chromophores which have an absorption and/or emission maxima in the visible to far infra-red range (includes the less than 600 nm range as well as 600-900 nm range) and sizes from 10-5000 nm (col. 1 line 9-56, col. 54 line 27-33). The contrast agents can be used for imaging a human or an animal and can be used for detecting the sentinel lymph node (col. 8 line 33-35, col. 8 line 55-59).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 3768

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 4, 6, 8, and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow. Snow discloses most of what is claimed as discussed above except for explicitly disclosing using particles that have at least part of the surface constituted by organopolysiloxane. Snow does disclose that the particles can comprise polymeric units such as polysiloxane (col. 47 line 15) so it would therefore be obvious to use any well known polysiloxane such as organopolysiloxane.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 3768

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline Cheng/
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768